IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

KELLI BAUGH and JUSTIN BAUGH,	)	
	)	**Civil Action No. 4:11-cv-00525-RBH**
Plaintiff(s),	)	
	)	
v.	)	
	)	
BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., and BERLEX, INC.,	)	
	)	
Defendants.	)	
	)	

DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT FOR LACK OF PROXIMATE CAUSE

Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") files this Reply in response to plaintiffs' Opposition to its motion for summary judgment, ECF No. 72, and in further support of its Motion and Opening Memorandum, ECF Nos. 70 & 70-1.

SUMMARY OF ARGUMENT

To prevail in this failure–to–warn case, plaintiffs must prove that a different warning would have changed Dr. Anu Chaudhry's decision to prescribe Mirena® for Ms. Baugh. In this Motion, Bayer asserts that there is no evidence that any additional warning by Bayer would have altered Dr. Chaudhry's prescribing decision. Because plaintiffs failed to come forward with evidence to demonstrate otherwise, Bayer is entitled to summary judgment. [1]

[1] Plaintiffs' brief contains a number of factual and legal inaccuracies that are irrelevant to the instant motion. Bayer does not waive any opposition to the inaccuracies, but will not address them in this briefing.

ARGUMENT

I. This Motion is Not Premature.

Bayer contends that summary judgment is appropriate because plaintiffs cannot establish that Bayer's allegedly inadequate warning was the proximate cause of their injuries. Under the learned intermediary doctrine, plaintiffs must establish proximate cause through the prescribing physician. That physician, Dr. Chaudhry, is the *only* witness who matters for this motion. *See Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 503 (D.S.C. 2012) (noting plaintiff's "failure to warn claim can succeed only if she can demonstrate that an adequate warning would have altered [the sole prescribing physician's] prescription decision") (applying South Carolina law). Thus, plaintiffs' assertion that "hotly debated" issues "being investigated through discovery," Opp. at 5, preclude summary judgment is misplaced. Plaintiffs have taken the deposition of Dr. Chaudhry and there is no evidence that a different warning would have altered her prescribing decision. Ongoing discovery against Bayer will not change that fact. Bayer's motion is, therefore, ripe for determination on the record before the court.

II. Plaintiffs Must Prove that a Different Warning Would Have Prevented Dr. Chaudhry from Prescribing Mirena® for Ms. Baugh.

Under South Carolina law, plaintiffs have the burden to demonstrate that Bayer's alleged failure–to–warn was the proximate cause of plaintiffs' injury. *See Odom v. G.D. Searle Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *see also Fisher v. Pelstring*, 817 F. Supp. 2d 791, 811 (D.S.C. 2011) (noting burden remains on plaintiff) (citation omitted); *Sauls*, 846 F. Supp. 2d at 503 ("[A] plaintiff fails to carry her burden . . . in the absence of any evidence demonstrating how an adequate warning would have altered a physician's prescription decision.") (citation omitted).

Bayer's summary judgment motion asserts that plaintiffs have no evidence of proximate cause and, therefore, that summary judgment is appropriate because plaintiffs cannot prove a material element of their claim. Once Bayer establishes that summary judgment is appropriate, "the burden shifts to the non-movant to set forth specific facts showing that there is a genuine dispute for trial." *Belcher v. Pacileo*, No. 4:11-cv-01715-RBH, 2010 U.S. Dist. LEXIS 175085, at *4 (D.S.C. Dec. 10, 2012) (granting defendants' motion for summary judgment in part) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)) (J. Harwell) (attached as Exhibit 6 to Resp., ECF No. 72-6 at 3). To meet their burden, plaintiffs must come forward with "more than a scintilla of evidence." *Id.* at *5 (citation omitted). Moreover, the facts must be material to the issue before the court: "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

Plaintiffs have failed to carry their burden to preclude the entry of summary judgment. There is no evidence that a different warning from Bayer would have changed Dr. Chaudhry's decision to prescribe Ms. Baugh Mirena® in November, 2005. The only evidence that plaintiffs present on this issue is insufficient to create a genuine issue of fact on proximate cause. Specifically, plaintiffs oppose summary judgment based on the following exchange:

> Q. If Bayer had provided you information that Mirena perforation could occur in a number that was greater than one in 1,000, would that have affected your prescribing decision for Mirena?
>
> A. Well, I guess the side effects would become a larger issue then.

Opp. at 15 (quoting Chaudhry Dep. at 177:17-23 (attached as Exhibit 10 to Opp., ECF 72-10 at 8)).

The quoted text does not meet plaintiffs' burden. Plaintiffs must prove that a warning about "spontaneous migration" would have deterred Dr. Chaudhry from prescribing Mirena. *See, e.g.*, Opp. at 15 (admitting plaintiffs' "burden to show that the non-disclosed risk of spontaneous migration was sufficiently important that it would have changed Dr. Chaudhry's prescribing decision"). The question plaintiffs rely on does not address their claims in the case. The question never mentions "spontaneous migration." Nor does it provide specifics on the topic addressed. Plaintiffs never presented Dr. Chaudhry with any literature documenting an increased rate of perforation for Mirena®. The question did not indicate if the alleged "greater" number of perforations totaled one or something else. So Dr. Chaudhry is left to "guess" in an attempt to answer the question. Therefore, her answer is non-specific. Further, plaintiffs never explored what the side effects becoming a "larger issue" means nor what impact that "larger issue" would have on Dr. Chaudhry's prescribing decision. *See Belcher*, 2012 U.S. Dist. LEXIS 175085, at *5. Dr. Chaudhry's "guess" about the significance of speculative and undefined information, as presented to her by plaintiff's counsel, is insufficient to present a genuine issue of material fact for trial.[2] Plaintiffs provide no other evidence to their burden of showing that a different warning would have changed Dr. Chaudhry's prescribing decision.

Instead of addressing proximate cause, plaintiffs devote the bulk of their brief to arguing that Bayer's warning was inadequate. *See* Opp. at 7-18. Yet, these arguments are irrelevant to the proximate cause issue. Indeed, the proximate cause issue assumes that the warning was inadequate and, instead, focuses on the impact of that inadequate warning on the physician's

[2] Dr. Chaudhry testified that she still prescribes Mirena® today. *See* Opening Mem. at 4 (citing Dr. Chaudhry's testimony). Dr. Chaudhry's continued use of Mirena® is further proof that plaintiffs have no evidence to support their speculative claim that additional information would have changed Dr. Chaudhry's Mirena® prescribing decisions.

decision to prescribe. Even assuming *arguendo* that Bayer's perforation warning[3] was inadequate, plaintiffs have failed to show that an adequate, or even a different, warning would have resulting in a decision not to prescribe Ms. Baugh Mirena®. Absent such evidence, plaintiffs' case fails.[4]

Both *Odom* and *Fischer* support Bayer's position on proximate cause. *See Odom*, 979 F.2d at 1003 (noting the "sole issue in this case, therefore, is whether an adequate warning to [plaintiff's] doctor about the risk . . . would have deterred [her] from prescribing the IUD"); *see also Fisher*, 817 F. Supp. 2d at 811 ("'[T]he burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.'") (citation omitted).[5]

CONCLUSION

For the reasons set forth above and in Bayer's Opening Memorandum, Bayer requests that the Court grant its motion for summary judgment pursuant to Rule 56(a).

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[3] Throughout the deposition of Dr. Chaudhry, plaintiffs never defined the term "spontaneous migration," never presented Dr. Chaudhry with medical literature documenting that such a condition exists, and never asked Dr. Chaudhry if a warning on "spontaneous migration" would have provided her with more information than is already include in the label. In sum, plaintiffs have nothing more than speculation and argument that Bayer's warning was inadequate.

[4] Although not relevant to this motion, Bayer notes that it has at all times warned of the risk of perforation, which is contained in a separate, bolded, and numbered section of its FDA-approved Mirena® label. *See* Opp. at 16. The label in place at the time of Ms. Baugh's insertion warned that Mirena® "may perforate the uterus or cervix, most-often during insertion . . . ." *Id.* Plaintiffs' mischaracterization of a non-physician, non Rule 30(b)(6) witness' testimony regarding vaguely remembered conversations that occurred more than 6 years ago, *see, e.g.*, Opp. at 10, cannot preclude summary judgment.

[5] In addition, Dr. Chaudhry testified that she was aware that perforation after insertion was a risk associated with Mirena®. *See* Chaudhry Dep. 52:17 – 53:11 ("at some point after the insertion . . . yes, it was common knowledge that what we call it could be perforation . . . .") (emphasis added) (attached as Exhibit 2 to Opening Mem., ECF No. 70-2 at 7); *see also Odom*, 979 F.2d at 1003 ("[T]he manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk") (citation omitted).

Respectfully submitted,

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